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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,821	01/26/2004	David K. Gardner	033948-0126	6872

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,821	GARDNER ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-17 and 21-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,14-17 and 21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/2/04 and 3/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 5/3/2006.

The amendment filed 5/3/2006 is acknowledged and has been entered.

Claims 1-12, 14-17, and 21-29 are currently pending in the application and are addressed herein.

Election/Restrictions

It noted that applicants have cancelled all claims except the claims that were grouped together as Group I. Furthermore, new claims 21-29 belong with Group I. As such the cancellation of the claims not encompassed by Group I renders the restriction requirement moot.

Claims 1-12, 14-17, 21-29 are currently and are examined herein.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/2/04 and 3/25/05 are acknowledged. It is noted the Japanese patents provided (see 3/25/05 IDS) only comprise an English translation of the abstract. Therefore, the Japanese patents have not been considered the Examiner. The examiner has considered all other references.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 4, 14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by European Patent No. EP 0 947 581 A1 (Amatsuji et al.; cited in 7/02/04 IDS).

3. Claim 1 is drawn to a mammalian culture medium comprising recombinant human albumin and a medium that can support cell development wherein the mammalian culture medium supports gametes and embryonic cell development and wherein the culture medium is free from non-recombinant human albumin. Claim 3 indicates that the medium supports embryo development. Claim 4 indicates that the medium supports mammalian stem cell development. Claim 14 is drawn to a mammalian culture medium supplement recombinant human albumin wherein the supplement is free from non-recombinant human albumin and wherein the replacement of serum albumin purified from blood by the supplement in a gamete or embryonic cell culture medium containing serum albumin purified from blood provides a supplemented culture medium that provides equivalent or enhanced gamete or embryonic cell development compared to the gamete or embryonic cell culture medium containing the serum albumin purified from blood. Claim 17 indicates that the recombinant human albumin in the supplement is in a range of about .0125 mg/ml to about 11.5 mg/ml when added to the medium.

4. Amatsuji teaches a serum-free mammalian culture medium containing recombinant human albumin which is free of non-recombinant human albumin (e.g., see abstract; p. 2 first column; p. 2, second column, etc.). Amatsuji teaches that the concentration of the recombinant human albumin is present in a range of 0.1-5g/L (e.g., see paragraph [0023]). It is noted that Amatsuji does not teach that the medium can be used to support gamete, embryonic cell development, mammalian stem cell development; nor does Amatsuji teach that using

recombinant human albumin instead of serum albumin would result in a equivalent or enhanced gamete/embryonic cell development.

Applicant is reminded that MPEP 2112.01 teaches "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'" In the instant case, Amatsuji teaches a composition comprising all of the structural limitations of the instant claims. Since the medium taught by Amatsuji meets all of the structural limitations of the claims, it would (absent evidence to the contrary) necessarily have the same functional properties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent No. EP 0 947 581 A1 (Amatsuji et al.; cited in 7/02/04 IDS) in view of Ellington et al. (US Patent 6,140,121; cited in the 7/02/04 IDS).

As indicated above, Amatsuji teaches a serum-free mammalian culture medium containing recombinant human albumin which is free of non-recombinant human albumin (e.g., see abstract; p. 2 first column; p. 2, second column, etc.). Amatsuji teaches that the basic medium can be any known medium for cell culture (e.g., see column 4, lines 1-5).

Amatsuji does not teach that the basic medium can be one of the medias listed in claim 2, such as Ham's F-10, Earl's, Whitten's or PBS.

Ellington teaches a medium for culturing mammalian cells, including gametes and embryos such wherein the base medium can be Ham's F-10, Earl's, Whitten's or PBS (e.g., see col. 16, 13-19).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Amatsuji and Ellington to create the claimed medium by substituting the base medium used by Amatsuji with Ham's F-10, Earl's, Whitten's or PBS, as taught by Ellington, with a reasonable expectation of success.

The motivation to combine the references to create claimed invention is provided by Amatsuji who teaches Amatsuji teaches that the basic medium can be any known medium for cell culture (e.g., see column 4, lines 1-5).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 14-17, 21-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,762,053 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '053 patent teaches a mammalian culture medium and supplement comprising recombinant human albumin and fermented hyaluronan wherein the medium is free on non-recombinant human albumin and wherein the medium increases the viability of gametes or embryonic cells. The instant claims are drawn to a mammalian culture medium comprising recombinant human albumin and a medium that can support cell development wherein the

mammalian culture medium supports gametes and embryonic cell development and wherein the culture medium is free from non-recombinant human albumin. Furthermore, all of the structural limitations set forth in the dependent claims (e.g., the type of cell culture medium used, the addition of citrate, the specific concentrations of reagents in the medium, etc.) are also encompassed or claimed in the patented claims.

Therefore, the claims of '053 patent are broader than the instant claims such that all of the embodiments of the instant claims are encompassed by the claims of the '053 patent. As such, the patented claims are a species of the instant claims. Since species anticipate the genus which they belong, the patented claims anticipate the instant claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON ANGELL
PATENT EXAMINER
AU1635